



**South Carolina Department of Health
and Environmental Control**

**Division of Procurement Services
Invitation for Bid
AMENDMENT ONE**

Solicitation No.: IFB-36586-08/11/2009-JS

Date Issued: August 4, 2009

Procurement Officer: Juanita Shealy, CPPB

Phone No.: (803) 898-3483

E-mail Address: shealyj2@dhec.sc.gov

Page No.: 1 of 4

DESCRIPTION: Contract to provide kits, reagents, and automated equipment needed to perform Dried Blood Spot Analysis of Biotinidase Deficiency Detection and Galactose-1-phosphate Uridyl Transferase Deficiency Detection in Newborn Screening.

USING GOVERNMENTAL UNIT: South Carolina Department of Health and Environmental Control

The Term "Offer" Means Your "Bid" or "Proposal". Your offer must be submitted in a sealed package. Solicitation Number & Opening Date must appear on package exterior. See "Submitting Your Offer" provision.

SUBMIT YOUR SEALED OFFER TO EITHER OF THE FOLLOWING ADDRESSES:

MAILING ADDRESS:

SC DHEC – Division of Procurement Services
Bureau of Business Management
2600 Bull Street
Columbia, S.C. 29201

PHYSICAL ADDRESS:

SC DHEC – Division of Procurement Services
Bureau of Business Management
2600 Bull Street, Room 1200 – Aycock Bldg.
Columbia, S.C. 29201

SUBMIT OFFER BY (Opening Date/Time) August 11, 2009 2:30 p.m. (See "Deadline For Submission Of Offer" provision)

QUESTIONS MUST BE RECEIVED BY: August 4, 2009 2:30 p.m. (See "Questions From Offerors" provision)

NUMBER OF COPIES TO BE SUBMITTED: One original and one copy marked "Copy".

CONFERENCE TYPE: Not Applicable

DATE & TIME:

LOCATION: Not Applicable

(As appropriate, see "Conferences - Pre-Bid/Proposal" & "Site Visit" provisions)

**AWARD &
AMENDMENTS**

Award will be posted on **August 18, 2009**. The award, this solicitation, any amendments, and any related notices will be posted at the following web address: <http://www.scdhec.net/procurement>

You must submit a signed copy of this form with Your Offer. By submitting a bid or proposal, You agree to be bound by the terms of the Solicitation. You agree to hold Your Offer open for a minimum of thirty (30) calendar days after the Opening Date.
(See "Signing Your Offer" and "Electronic Signature" provisions.)

NAME OF OFFEROR

(full legal name of business submitting the offer)

Any award issued will be issued to, and the contract will be formed with, the entity identified as the Offeror. The entity named as the offeror must be a single and distinct legal entity. Do not use the name of a branch office or a division of a larger entity if the branch or division is not a separate legal entity, i.e., a separate corporation, partnership, sole proprietorship, etc.

AUTHORIZED SIGNATURE

(Person must be authorized to submit binding offer to contract on behalf of Offeror.)

TAXPAYER IDENTIFICATION NO.

(See "Taxpayer Identification Number" provision)

TITLE

(business title of person signing above)

STATE VENDOR NO.

(Register to Obtain S.C. Vendor No. at www.procurement.sc.gov)

PRINTED NAME

(printed name of person signing above)

DATE SIGNED

STATE OF INCORPORATION

(If you are a corporation, identify the state of incorporation.)

OFFEROR'S TYPE OF ENTITY: (Check one)

(See "Signing Your Offer" provision.)

☐ Sole Proprietorship

☐ Partnership

☐ Other

☐ Corporate entity (not tax-exempt)

☐ Corporation (tax-exempt)

☐ Government entity (federal, state, or local)

PAGE TWO

(Return Page Two with Your Offer)

HOME OFFICE ADDRESS (Address for offeror's home office / principal place of business)	NOTICE ADDRESS (Address to which all procurement and contract related notices should be sent.) (See "Notice" clause)	
	Area Code - Number - Extension	Facsimile
	E-mail Address	

PAYMENT ADDRESS (Address to which payments will be sent.) (See "Payment" clause)	ORDER ADDRESS (Address to which purchase orders will be sent) (See "Purchase Orders and "Contract Documents" clauses)	
<input type="checkbox"/> Payment Address same as Home Office Address <input type="checkbox"/> Payment Address same as Notice Address (check only one)	<input type="checkbox"/> Order Address same as Home Office Address <input type="checkbox"/> Order Address same as Notice Address (check only one)	

ACKNOWLEDGMENT OF AMENDMENTS

Offerors acknowledges receipt of amendments by indicating amendment number and its date of issue. (See "Amendments to Solicitation" Provision)

Amendment No.	Amendment Issue Date	Amendment No.	Amendment Issue Date	Amendment No.	Amendment Issue Date	Amendment No.	Amendment Issue Date

DISCOUNT FOR PROMPT PAYMENT (See "Discount for Prompt Payment" clause)	10 Calendar Days (%)	20 Calendar Days (%)	30 Calendar Days (%)	____ Calendar Days (%)
--	----------------------	----------------------	----------------------	------------------------

PREFERENCES - SC RESIDENT VENDOR PREFERENCE (June 2005): Section 11-35-1524 provides a preference for offerors that qualify as a resident vendor. A resident vendor is an offeror that (a) is authorized to transact business within South Carolina, (b) maintains an office* in South Carolina, (c) either (1) maintains a minimum \$10,000.00 representative inventory at the time of the solicitation, or (2) is a manufacturer which is headquartered and has at least a ten million dollar payroll in South Carolina, and the product is made or processed from raw materials into a finished end-product by such manufacturer or an affiliate (as defined in Section 1563 of the Internal Revenue Code) of such manufacturer, and (d) has paid all assessed taxes. If applicable, preference will be applied as required by law.	OFFERORS REQUESTING THIS PREFERENCE MUST INITIAL HERE. _____ *ADDRESS AND PHONE OF IN-STATE OFFICE <input type="checkbox"/> In-State Office Address same as Home Office Address <input type="checkbox"/> In-State Office Address same as Notice Address (check only one)

PREFERENCES - SC/US END-PRODUCT (June 2005): Section 11-35-1524 provides a preference to vendors offering South Carolina end-products or US end-products, if those products are made, manufactured, or grown in SC or the US, respectively. An end-product is the item identified for acquisition in this solicitation, including all component parts in final form and ready for the use intended. The terms made, manufactured, and grown are defined by Section 11-35-1524(B). By signing your offer and checking the appropriate space(s) provided and identified on the bid schedule, offeror certifies that the end-product(s) is either made, manufactured or grown in South Carolina, or other states of the United States, as applicable. Preference will be applied as required by law.	IF THIS PREFERENCE APPLIES TO THIS PROCUREMENT, PART VII (BIDDING SCHEDULE) WILL INCLUDE A PLACE TO CLAIM THE PREFERENCE. OFFERORS REQUESTING THIS PREFERENCE MUST CHECK THE APPROPRIATE SPACES ON THE BIDDING SCHEDULE.
--	---

AMENDMENTS TO SOLICITATION (DHEC – FEB 2007)

- (a) The Solicitation may be amended at any time prior to opening. All actual and prospective Offerors should monitor the following web site for the issuance of Amendments: <http://www.scdhec.gov/procurement/>
- (b) Offerors shall acknowledge receipt of any amendment to this solicitation (1) by signing and returning the amendment, (2) by identifying the amendment number and date in the space provided for this purpose on Page Two, (3) by letter, or (4) by submitting a bid that indicates in some way that the bidder received the amendment.
- (c) If this solicitation is amended, then all terms and conditions which are not modified remain unchanged.

OPENING WILL REMAIN THE SAME - August 22, 2009 at 2:30 p.m.

The contract to provide kits, reagents, and automated equipment needed to perform Dried Blood Spot Analysis of Biotinidase Deficiency Detection and Galactose-1-phosphate Uridyl Transferase Deficiency Detection in Newborn Screening modifications to the solicitation are incorporated by this amendment.

1. Change on Page 14, Section III, Scope of Work/Specifications, Specifications - Renumbered.**A. Kits/Reagents Requirements:**

1. All reagents must be Food and Drug Administration (FDA) approved for clinical assays.
2. All kits and reagents must be from the same manufacturer.
3. All equipment must be compatible with the kits, reagents, and test methodologies.
4. Reagents must be currently available.
5. The bid price must include all controls, standards, calibrators, and instrumentation required to perform the tests in accordance with the manufacturer's package insert. ~~This includes any micro titer filter plates necessary to prepare samples for testing in accordance with the manufacturer's package insert.~~
6. Reagents supplied must be stable for the period listed in the package insert or on the reagent vial.
7. Controls must be supplied on Schleicher and Schuell (S&S) 903 filter paper or equivalent.
8. A minimum of two dried blood spot controls must be provided for both the Biotinidase and GALT assays.
9. Test kit must be compatible with the DBS (Dried Blood Spot) Punch Machine or equivalent following existing equipment used for sample preparation. (The use of micro titer plates is required.)
10. Reagents offered must have demonstrated at least one year of satisfactory performance with Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) approved Proficiency Testing (PT) Program, e.g. the Centers for Disease Control and Prevention (CDC) quality control programs.
11. The test protocol for the Biotinidase and GALT assays must be such that at least 500 specimens can be setup within one 7.5-hour workday. Protocol should utilize standard 1/8" or 1/4" dried blood spots.
12. Vendor agrees to ship once a quarter (unless batch shipment becomes necessary due to weather, strikes, etc) and will supply shipping schedules. Reagents must be shipped early in the week so they can be received during normal working hours to ensure proper storage. Each shipment must be accompanied by written documentation showing that all quality control parameters have been satisfied. The QC material must have a stable shelf life such that new lots can be received and validated against existing lots before expiration of existing material.
13. New lots of reagents will be assayed, when received, in the BOL to verify compliance to the parameters accompanying the reagents. Replacement of defective or inadequate reagents will be provided at no additional charge within twenty-four hours of notification. Unsuitable material will be returned to the vendor at the vendor's expense.
14. DHEC reserves the right to replace existing kits with new and updated kits as they become available. The contract administrator will issue the appropriate modifications to include quantities, stock numbers, and cost. If the vendor, at any time during the contract, would like to make any changes to the contract those changes including the item description, stock number, size, and cost must be submitted in writing to DHEC Division of Procurement Services. ~~These changes require the approval of the Materials Management Office, followed by a written signed amendment to the contract.~~
15. The South Carolina Department of Health and Environmental Control (DHEC) assumes no responsibility for products other than those covered by the contract and identified on DHEC's purchase order.
16. Orders will be placed by authorized personnel on an as-needed basis.
17. Each bidder is required to provide Material Safety Data Sheets (MSDS) documentation for all reagents used in the chemistry assays. Assays containing carcinogenic or otherwise environmentally hazardous reagents may be removed from consideration.

2. Change on Page 14, Section III, Scope of Work/Specifications, Specifications A.

Item 5. Above - Delete This includes any micro titer filter plates necessary to prepare samples for testing in accordance with the manufacturer's package insert.

Item 14. Above - Delete - These changes require the approval of the Materials Management Office, followed by a written signed amendment to the contract.

VIII. BIDDING SCHEDULE / PRICE-BUSINESS PROPOSAL**BIDDING SCHEDULE (NOV 2007)**

The cost per kit to be an all-inclusive for all required reagents, supplies, and equipment needed to perform the analysis for Dried Blood Spot Analysis of Biotinidase Deficiency Detection and Galactose-1-Phosphate Uridyl Transferase (GALT) Deficiency Detection in Newborn Screening according to the manufacturer's package insert.

Item 1. Biotinidase Deficiency Detection

Cost Per Test Kit: \$ _____

Tests/Kit: _____

Manufacturer's Name:	Product Number:
U.S. End Product? (Y/N) _____	S.C. End Product? (Y/N) _____

Item 2. Galactose-1-Phosphate Uridyl Transferase (GALT) Deficiency Detection

Cost Per Test Kit: \$ _____

Tests/Kit: _____

Manufacturer's Name:	Product Number:
U.S. End Product? (Y/N) _____	S.C. End Product? (Y/N) _____